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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-0307]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request Gonococcal Isolate Surveillance Project to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on February 5, 2018 to obtain comments from the public and affected agencies. The CDC received 2 non-substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Gonococcal Isolate Surveillance Project (0920-0307) (Exp. Date 02/28/2019) – Revision – National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Gonococcal Isolate Surveillance Project (GISP) was created in 1986 to monitor trends in antimicrobial susceptibilities of *Neisseria gonorrhoeae* strains in the United States. GISP continues to be a collaboration between different branches of the CDC Division of STD Prevention within the National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), selected regional laboratories and selected state/ local public health departments and their associated STD specialty care clinics in the U.S. National organizations, local jurisdictions and individuals use data collected in GISP to understand and prevent antibiotic resistance in *N. gonorrhoeae*. Data from GISP are used to establish a scientific basis for the selection of gonococcal therapies and to allow pro-active changes to treatment guidelines before widespread resistance and failures of treatment occur. To increase capacity to detect and monitor resistant gonorrhea and to improve the specificity of

GISP, this revision is being submitted to include collection of additional isolates and data elements.

In the current approval period, GISP isolates are only collected from males and include <4% of reported male gonorrhea cases in the United States. This relatively limited scope likely limits the speed with which new resistance patterns are found and with which public health officials can respond. Published data suggest that resistance in *N. gonorrhoeae* might develop initially in non-genital anatomic sites, such as the pharynx. It has also been hypothesized that susceptibility patterns may be different among women. Upon receiving OMB approval of the revision request, CDC plans to begin including isolates from the pharynx and other anatomic sites, as well as from women. These changes are expected to support public health efforts to detect and respond to resistance more quickly.

GISP surveillance can also be strengthened by ensuring that GISP surveillance is only being conducted on *N. gonorrhoeae* and not on other similar bacteria. *Neisseria meningitidis* can cause clinical syndromes that are indistinguishable from gonorrhea. Using nucleic acid amplification tests (a more specific diagnostic test) in conjunction with bacterial culture from all anatomic sites can ensure that non-gonococcal bacteria are excluded from GISP data. This is expected to strengthen the accuracy and usefulness of GISP data.

Historically, healthcare providers at approximately 30 participating sentinel sites (i.e., STD clinic or multiple STD clinics affiliated with a single public health department) obtain urethral *N. gonorrhoeae* isolates from the first 25 men with urethral gonorrhea each month with occasional month-to-month variability. With this revision, we are now asking for a subset of sentinel sites (10 out of 30 sites) to conduct enhanced surveillance activities, collecting additional isolates (including from the pharynx, rectum, and cervix of exposed persons) with a limited number of additional data elements. We anticipate that approximately 50 additional isolates per month will be collected by each of these 10 sites (total of approximately 70 isolates per month per enhanced surveillance site). All isolates will be shipped each month to a regional laboratory for antimicrobial susceptibility testing. When isolates that appear to be bacteria other than *N. gonorrhoeae* are identified at one of the ten sentinel sites conducting enhanced surveillance, the isolate will be shipped to the regional laboratory and then to CDC. Based on informal discussions with current GISP sentinel sites, we anticipate that approximately 10 such isolates will be identified at each site per year. Sentinel sites that are not part of this small subset will continue to function as they already are.

Under this revision, the data collection and reporting processes have been streamlined to minimize burden. All demographic/clinical data from the sentinel sites, and antimicrobial susceptibility testing results from the regional laboratories, will be submitted electronically (1) directly from the sentinel site to the GISP data manager at CDC through a secure data portal, (2) through a secure GISP-web based application, or (3) through the CDC Secure Access Management Services partner portal. To minimize burden, comma-separated values (csv) files that provide standardized structure of the electronic data are provided to sentinel sites and laboratories. Additionally, to further minimize burden, the regional laboratories will be able to extract electronic data from electronic laboratory information systems instead of hand entering data and will no longer be required to report control strain testing results.

This project will not collect name, social security number, or date of birth. A Patient ID, a unique patient identifier assigned by the site that allows for linking of multiple isolates from a single person at a single clinic visit and across multiple clinic visits, is requested and will be provided to CDC for purposes of enhanced surveillance. Sensitive information such as sex of sex partners, HIV status, sex work exposure, and injection drug use are collected. Patient data are

obtained through review of medical records by the clinic staff and included in collection reporting of demographic/clinical information. All personally identifiable information (PII) is retained by the STD clinics that treated the patient and is not recorded with data sent to CDC or regional laboratories. At sites where enhanced surveillance will not occur isolates are collected from patients as part of their routine care when a gonorrhea infection is suspected. The electronic GISP database is stored on the CDC mainframe computer and only approved Division of STD Prevention (DSTDP) staff have access rights to the data. As part of the revision, we will continue to systematically identify the risks and potential effects of collecting, maintaining, and disseminating PII and to examine and evaluate alternative processes for handling that information to mitigate potential privacy risks and risks to confidentiality.

The CDC has designated *N. gonorrhoeae* as one of three "urgent" antibiotic resistance threats in the United States. The CDC is requesting a three-year OMB approval for this revision, which directly responds to the National Strategy for Combating Antibiotic Resistant Bacteria by improving and strengthening surveillance of antimicrobial resistance through GISP. This GISP data can help monitor and evaluate the effectiveness of public health interventions conducted to support the National Strategy

for Combating Antibiotic-Resistant Bacteria. Sentinel sites and regional laboratories voluntarily apply to participate in the GISP cooperative agreement program. Once funded, participation in the GISP information collection and isolate processing plan is required.The total estimated annualized burden hours are 11,376. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Sentinel site conducting core surveillance	Demographic/ Clinical Data	20	240	11/60
Sentinel site conducting enhanced surveillance	Demographic/ Clinical Data	10	840	12/60
Regional laboratory	Antimicrobial Susceptibility Testing Results	4	3,300	40/60
Regional laboratory	Control Strain Susceptibility Testing	4	48	5/60

Jeffrey M. Zirger,

Acting Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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